The Regulations of Connect cut State Agencies are amended by adding section 22a-153-8, as follows:

(NEW)

Sec. 22a-153-8. Use of radionuclides in the healing arts.

(a) Definitions.

Terms used in the section that are not defined in this section are as provided in section 22a-153-1 and section 22a-153-2 of the Regulations of Connecticut State Agencies. For the purposes of this section, the following definitions also apply:

(1) "Address of use" means the building or buildings that are identified on a registration or license and where radioactive material may be produced, prepared, received, used or stored.

(2) "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using or storing radioactive material.

(3) "Authorized medical physicist" means "authorized medical physicist" as defined in section 22a-153-7 of the Regulations of Connecticut State Agencies.

(4) "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in subsection (f)(3) or (f)(4) of this section;

(2) Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Commissioner, NRC or an Agreement State or Licensing State; or

(3) Is identified as an authorized nuclear pharmacist on a permit issued by an Commissioner, NRC or an Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(5) "Authorized user" means a physician, dentist or podiatrist who:

(1) Meets the requirements in subsection (f)(5) and subsections (h)(3)(A), (i)(4)(A),(j)(4),(j)(5), (j)(6), (k)(9), (k)(10), (l)(2)(A) and (m)(17)(A) of this section;

(2) Is identified as an authorized user on a license or equivalent permit or registration issued by the Commissioner, NRC or an Agreement State or Licensing State; or

(3) Is identified as an authorized user on a permit issued by the Commissioner, NRC or an Agreement State or Licensing State specific license of broad scope that is authorized to permit the medical use of radioactive material.

(6) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(7) "Client's address" means the address of use or a temporary jobsite for the purpose of providing mobile medical service as provided in 10 CFR 35.80.

(8) "Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(9) "Dentist" means an individual licensed to practice dentistry or dental medicine pursuant to section 20-106 of the Connecticut General Statutes.

(10) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method and other instructions and precautions by which the registrant or licensee performs diagnostic clinical procedures.

(11) "High dose-rate remote afterloader" or "HDR" means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

(12) "Low dose-rate remote afterloader" or "LDR" means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

(13) "Management" means the chief executive officer or other individual having the authority to manage, direct or administer a registrant or licensee's activities, or such persons' delegate or delegates.

(14) "Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually applied or inserted.

(15) "Medical event" means "medical event" as defined in 10 CFR 35.3045(a).

(16) "Medical institution" means an organization in which several medical disciplines are practiced.

(17) "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(18) "Medium dose-rate remote afterloader" or "MDR" means a device that remotely delivers a

dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

(19) "Mobile medical service" means the transportation of radioactive material or its medical use at the client's address.

(20) "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(21) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(22) "Pharmacist" means "pharmacist" as defined in section 20-571 of the Connecticut General Statutes.

(23) "Physician" means "physician" as defined in section 20-571 of the Connecticut General Statutes.

(24) "Podiatrist" means a doctor of "podiatric medicine" as defined in section 20-50 of the Connecticut General Statutes.

(25) "Preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

(26) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical drug as documented:

(1) In a written directive as specified in subsection (e)(5) of this section; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to subsections (h)(1), (i)(1) and (j)(1) of this section.

(27) "Prescribed dose" means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or

the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(28) "Pulsed dose-rate remote afterloader" or "PDR" means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(29) "Radiation Safety Officer" or "RSO" means an individual who:

(1) Meets the requirements in subsection (m) or (p) of this section; or

(2) Is identified as a Radiation Safety Officer on a NRC or Agreement State license or other equivalent permit, license or registration recognized by the Commissioner for similar types and uses of radioactive material.

(30) "Radioactive drug" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment or prevention of disease or other abnormal condition.

(31) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(32) "Sealed Source and Device Registry" means the national registry that contains the registration certificates maintained by the NRC, which summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for such products.

(33) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to deliver a dose to a treatment site with precision.

(34) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(35) "Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(36) "Temporary jobsite" means a location where mobile medical services are conducted in addition to the location(s) of use authorized on a registration or license.

(37) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(38) "Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(39) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(40) "Type of use" means use of radioactive material as specified under G.44, G.47, G.52, G.59, G.69, G.71 or G.89.

(41) "Unit dosage" means a dosage that is administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(42) "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (j) of this section.

(1) Any record, report or document required by this section shall be maintained for a minimum of five (5) years in a form that is the original, a reproduced copy, a microform or stored in electronic media with the capability for producing legible, accurate and complete records.

(2) Any record, report or document required pursuant to this section shall include a certification signed by a responsible corporate officer or a duly authorized representative of such officer, as those terms are defined in section 22a-430-3(b)(2) of the Regulations of Connecticut State Agencies, and by the individual or individuals responsible for actually preparing such document or record, each of whom shall examine and be familiar with the information submitted and all attachments thereto, and shall make inquiry of those individuals responsible for obtaining the information to determine that the information is true, accurate and complete, and each of whom shall certify in writing as follows:

> "I have personally examined and am familiar with the information submitted in this document and all attachments thereto, and I certify that based on reasonable investigation, including my inquiry of those individuals responsible for obtaining the information, the submitted information is true, accurate and complete to the best of my knowledge and belief. I understand that any false statement made in the submitted information may be punishable as a criminal offense under section 22a-175 of the Connecticut General Statutes, under section 53a-157b of the Connecticut General Statutes, and in accordance with any other applicable statute."

(c) Research involving human subjects. The requirements of this section apply only to the use of radionuclides in or on human subjects. A registrant or licensee may conduct research involving human subjects using radioactive materials in accordance with the requirements of this section provided the registrant or licensee meets the following requirements:

(1) The registrant or licensee shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects, and the research is authorized according to one of the following requirements:

(A) The research is conducted, funded, supported or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects; or

(B) A registrant or licensee shall apply for and receive approval of a specific amendment to a license or registration issued by the Department before conducting such research. ;

(2) Any research involving human subjects authorized in subsection (c)(1) of this section shall be conducted using radioactive material authorized for medical use in the license or registration; and

(3) Nothing in this subsection relieves a registrant or licensee from the duty to comply with all applicable state and federal requirements governing radioactive drugs or devices.

(d) Licensing.

(1) No person shall manufacture, produce, prepare, acquire, receive, possess, use or transfer radioactive material for medical use without having been issued a registration or a specific license issued by the Department, the NRC, an Agreement State or as allowed in subsection (d)(2) or (d)(3) of this section.

(2) An individual may receive, possess, use or transfer radioactive material in accordance with the regulations in this section under the supervision of an authorized user as provided in subsection (i) of this section**,** unless prohibited by registration or license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the requirements in this section under the supervision of an authorized nuclear pharmacist or authorized user as provided in subsection (i) of this section, unless prohibited by registration or license condition.

(4) An application for a registration or license as required by subdivision (1) of this subsection shall be made by filing a form prepared by the Commissioner.

(e) Exemptions.

The Commissioner may, upon application of any interested person or upon his own initiative, grant such exemptions from this section as he determines are authorized by law, not endangering life or property or the common defense and security and otherwise in the public interest.

(f) Registrant or licensee radiation protection program responsibilities.

(1) In addition to the radiation protection program requirements of section 22a-153-2(d) of the Regulations of Connecticut State Agencies, a registrant or licensee's management must approve in writing:

(A) Requests for a registration or license application, renewal or amendment before submittal to the Commissioner;

(B) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

(C) Radiation protection program changes that do not require an amendment and are permitted under subsection (g) of this section.

(2) A registrant or licensee's management shall appoint a Radiation Safety Officer who agrees in writing to be responsible for implementing the radiation protection program. The registrant or licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulations.

(3) For up to sixty (60) days each year, a registrant or licensee may permit an authorized user or another qualified individual to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in subdivision (5) of this subsection, provided the licensee takes the actions required in subdivisions (2), (4), (5) and (8) of this subsection. A registrant or licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the registration or license.

(4) A registrant or licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(5) A registrant or licensee shall provide the Radiation Safety Officer sufficient authority and resources, to:

(A) Identify radiation safety problems;

(B) Initiate, recommend or provide corrective actions;

(C) Stop unsafe operations; and

(D) Verify implementation of corrective actions.

(6) Any registrant or licensee that is authorized for two or more different types of radioactive material use under subsections (ff), (gg), (ii) and (jj) of this section or two or more types of units under subsection (ii) of this section shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the registration or license. Such a committee must include an authorized user of each type of use permitted by the registration or license, the Radiation Safety Officer, a representative of the nursing service and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the registrant or licensee deems appropriate.

(7)A registrant or licensee's Radiation Safety Committee shall meet at intervals not to exceed six (6) months. The registrant or licensee shall maintain and record minutes of each meeting.

(8) A registrant or licensee shall retain a record of actions taken pursuant to subdivisions (1), (2) and (4) of this subsection as required by subsection (kk) of this section.

(g) Revision of radiation protection program.

(1) A registrant or licensee may revise its radiation protection program without approval of the Commissioner if:

(A) The revision is in compliance with regulations promulgated under section 22a-153 of the Connecticut General Statutes and the registration or license;

(B) The revision has been reviewed and approved by the Radiation Safety Officer, management and Radiation Safety Committee; and

(C) The affected individuals are instructed on the revised program before the changes are implemented.

(2) A registrant or licensee shall retain a record of each change in accordance with subsection (17)(kk)(3) of this section.

(h) Duties of an authorized user and authorized medical physicist.

(1) A registrant or licensee shall assure that only authorized users for the type of radioactive material used:

(A) Prescribe the radiopharmaceutical dosage or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;

(B) Direct, as specified in subsections (i) or (j) of this section, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and

(C) Prepare and administer, or supervise the preparation and administration of, radioactive material for medical use in accordance with subsections (d)(2), (d)(3) and (i) of this section.

(2) A registrant or licensee shall allow that only an authorized medical physicist, or in the case of subparagraph (C) of this subdivision, the RSO, as applicable, perform:

(A) Full calibration measurements as described in subsections (ii)(7), (ii)(8) and (ii)(9) of this section;

(B) Periodic spot checks as described in subsections (ii)(10), (ii)(11) and (ii)(12) of this section; and

(C) Radiation surveys as described in subsection (ii)(14) of this section.

(i) Supervision.

(1) A registrant or licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by subsection (d) of this section shall:

(A) In addition to the requirements in 19 CFR 12, instruct the supervised individual in the registrant or licensee's written radiation protection procedures, written directive procedures, requirements of this section and registration or license conditions with respect to the use of radioactive material; and

(B) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, requirements of this section and registration or license conditions with respect to the medical use of radioactive material.

(2) A registrant or licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by subsection (d)(3) of this section, shall:

(A) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(B) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, this section and registration or license conditions.

(3) A registrant or licensee that permits supervised activities under subdivisions (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(j) Written directives.

(1) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(2) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible, and in no event in more than forty-eight (48) hours after following the oral directive, in writing signed and dated in the patient's record.

(3) The written directive must contain the patient or human research subject's name and the following information:

(A) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131, the dosage;

(B) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-13, the radioactive drug, dosage and route of administration;

(C) For gamma stereotactic radiosurgery, the total dose, treatment site and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(D) For teletherapy, the total dose, dose per fraction, number of fractions and treatment site;

(E) For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions and total dose; or

(F) For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:

(i) Before implantation, the treatment site, the radionuclide and dose, and

(ii) After implantation but before completion of the procedure, the radionuclide, treatment site, number of sources and total source strength and exposure time or the total dose.

(4) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose.

(5) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented and signed by the authorized user as soon as possible, but in no event in more than forty-eight (48) hours of the oral revision, in the patient's record.

(6) The registrant or licensee shall retain a copy of the written directive in accordance with the recordkeeping requirements of this section.

(k**) Procedures for administrations requiring a written directive.**

(1) For any administration requiring a written directive, the registrant or licensee shall develop, implement and maintain written procedures to provide high confidence that:

(A) The patient's or human research subject's identity is verified before each administration; and

(B) Each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by subdivision (1) of this subsection must address the following items as applicable to the registrant or licensee's use of byproduct material:

(A) Verifying the identity of the patient or human research subject;

(B) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(C) Checking both manual and computer-generated dose calculations; and

(D) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

(3) A registrant or licensee shall retain a copy of the procedures required under subdivision (1) of this subsection in accordance with the recordkeeping requirements of this section.

(l) Suppliers for sealed sources or devices for medical use. For medical use, a licensee may only use:

(1) Sealed sources or devices initially manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State or a Licensing State;

(2) Sealed sources or devices noncommercially transferred from a licensee holding a license issued under 10 CFR 35; or

(3) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR 30 or the equivalent requirements of an Agreement State or a Licensing State;

(m) Training for Radiation Safety Officer. Except as provided in subsection (q) of this section, a registrant or licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in subsection (f) of this section to be an individual who:

(1) Is certified by a specialty board whose certification process includes all of the requirements in subdivision (2) of this subsection and whose certification has been recognized by the NRC or an Agreement State, or;

(2) Has completed a structured educational program meeting the following requirements of this subdivision and subdivision (3) of this subsection:

(A) 200 hours of didactic training in the following areas:

(i) Radiation physics and instrumentation,

(ii) Radiation protection,

(iii) Mathematics pertaining to the use and measurement of radioactivity,

(iv) Radiation biology, and

(v) Radiation dosimetry; and

(B) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Nuclear Regulatory Commission or Agreement State license that authorizes similar type(s) of use(s) of radioactive material involving the following:

(i) Shipping, receiving and performing related radiation surveys,

(ii) Using and performing checks for proper operation of dose calibrators, survey meters and instruments used to measure radionuclides,

(iii) Securing and controlling radioactive material,

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material,

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures,

(vi) Using emergency procedures to control radioactive material, and

(vii) Disposing of radioactive material; and

(3) Has obtained written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in subdivision (2) of this subsection and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for medical uses of radioactive material; or

(4) As an alternative to meeting the requirements of subdivision (1) or subdivisions (2) and (3) of this subsection, an authorized user, authorized medical physicist or authorized nuclear pharmacist identified on an applicable registration or license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

(n) Training for an authorized medical physicist. The registrant or licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process includes all of the training and experience requirements in subdivision (2) of this subsection and whose certification has been recognized by the NRC or an Agreement State; or

(2) Meets the following requirements:

(A) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics or health physics, or an equivalent training program approved by the Commissioner, another Agreement State or the NRC and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in **G.36, G.64e.,G.77, G.78, G.79, G.80, G.81, G.82 and G.84**, subsections (v), (gg)(6)(E), (ii)(7), (ii)(8) of this section, as applicable; and (ii)(9), (ii)(10), (ii)(11), (ii)(12), (ii)(14).

(B) Has obtained a written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in subdivision (2)(A) of this subsection and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each

type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

(o) Training for an authorized nuclear pharmacist. The registrant or licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in subdivision (2) of this subsection and whose certification has been recognized by the NRC or an Agreement State; or

(2) The individual has:

(A) Completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving:

(a) Shipping, receiving and performing related radiation surveys,

(b) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides,

(c) Calculating, assaying and safely preparing dosages for patients or human research subjects,

(d) Using administrative controls to avoid medical events in the administration of radioactive material, and

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(B) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subdivision (2)(A) of this subsection and has achieved a level of competency sufficient to operate a nuclear pharmacy independently.

(p) Exceptions from training requirements.

(1) An individual identified as a Radiation Safety Officer, a medical physicist or a nuclear pharmacist on a NRC, an Agreement State license or on a permit issued by a NRC or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, prior

to the effective date of this section is exempt from the training requirements of subsections (m), (n) and (o) of this section, respectively.

(2) Physicians, dentists or podiatrists identified as authorized users for the medical, dental or podiatric use of radioactive material on a NRC or Agreement State license or on a permit issued by a NRC or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, issued prior to the effective date of this section who perform only those medical uses for which they were authorized are exempt from the training requirements of G.46, G.51, G.56, G.57, G.58, G.67, G.68, G.70 and G.88.

(q) Recentness of Training. The training and experience specified in this section must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

(r) Possession, use and testing of instruments to measure the activity of unsealed radioactive materials. Each licensee or registrant shall:

(1) For direct measurements performed in accordance with subsection (t) of this section, possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject;

(2) Test the instrumentation required in subdivision (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions;

(3) In the tests required in subdivision (2) of this subsection, include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument; and

(4) Retain a record of each instrument test required by this subsection in accordance with G.95.

(s) Calibration of survey instruments. Each registrant or licensee shall calibrate survey instruments as follows:

(1) Survey instruments used to show compliance with this section and section 22a-153-2 of the Regulations of Connecticut State Agencies shall have been calibrated before first use, annually and following any repair that will affect the calibration;

(2) To satisfy the requirements of subdivision (1) of this subsection:

(A) Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

(B) Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed **12 months** or after instrument servicing, except for battery changes,

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour, and

(iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

(C) Conspicuously note on the instrument the date of calibration;

(3) Survey instruments shall not be used if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent; and

(4) Retain a record of each survey instrument calibration in accordance with G.96.

(t) Determination of dosages of radioactive material for medical use. Each registrant or licensee shall determine radioactive material dosages for medical use as follows:

(1) Determine and record the activity of each dosage prior to medical use;

(2) For a unit dosage, a determination required by subdivision (1) of this subsection shall be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent provisions of the NRC, Agreement State or Licensing State;

(3) For other than unit dosages, a determination required by subdivision (1) of this subsection shall be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent provisions of the NRC, Agreement State or Licensing State;

(4) Unless otherwise directed by the authorized user, no dosage that differs from the prescribed dosage by more than 20 percent shall be used; and

(5) Retain a record of the dosage determination required by this section in accordance with G.97.

(u) Authorization for calibration, transmission and reference sources. Any person authorized by subsection (d) of this section for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 10 CFR 35.74 or equivalent provisions of the NRC, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerels (30 mCi) each;

(2) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

(3) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

(A) 7.4 megabecquerels (200 µCi); or

(B) 1000 times the quantities in Appendix B of 10 CFR 30; and

(4) Technetium-99m in amounts as needed.

(v) Requirements for possession of sealed sources and brachytherapy sources. A registrant or licensee in possession of a sealed source or brachytherapy source shall:

(1) Follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Commissioner;

(2) For possession of a sealed source :

(A) Test the source for leakage in accordance with section 22a-153-2 of the Regulations of Connecticut State Agencies; and

(B) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commissioner, an Agreement State, a Licensing State or the NRC in the Sealed Source and Device Registry;

(3) If the leak test reveals the presence of 185 becquerels (4.99×10^{-9} Ci) or more of removable contamination:

(A) Immediately withdraw the sealed source from use and store, dispose or cause it to be repaired in accordance with the requirements of 10 CFR 10 and 10 CFR 20; and

(b) File a report with the Commissioner within five days of receiving the leak tests results in accordance with G.121; and

(4) Except for gamma stereotactic radiosurgery sources, conduct a semi-annual physical inventory of all sources and retain each inventory record in accordance with G.98.

(w) Labels. A registrant or licensee shall label each syringe and vial that contains a radioactive drug to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(x) Vial shields. A registrant or licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield, as practical.

(y) Surveys for ambient radiation dose rate and contamination. Each registrant or licensee shall conduct surveys for ambient radiation dose rate and contamination as follows:

(1) With a radiation detection survey instrument at the end of each day of use in all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered;

(2) Conduct the surveys required by subdivision (1) of this subsection so as to able to measure dose rates as low as one microsievert (0.1 mrem) per hour;

(3) Establish dose rate action levels for the surveys required by subdivision (1) of this subsection and require that the individual performing the survey immediately notify the RSO if a dose rate exceeds an action level;

(4) Survey for removable contamination each week of use in all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored;

(5) Establish removable contamination action levels for the surveys required by subdivision (4) of this subsection and require that the individual performing the survey immediately notify the RSO contamination exceeds action levels;

(6) If patients or human research subjects are confined when they cannot be released pursuant to subsection (z) of this section, the surveys required by subdivision (1) of this subsection are not required; and

(7) Retain a record of each survey in accordance with (kk)(10).

(z) Release of individuals containing radioactive drugs or implants. A registrant or licensee may authorize the release from its control of an individual who has been administered unsealed byproduct material or impacts containing byproduct material if such release meets the requirements of 10 CFR 35.75.

(aa) Mobile medical service technical requirements. A registrant or licensee providing mobile medical service shall meet the requirements of 10 CFR 35.80.

(bb) Storage and control of volatiles and gases. Each licensee or registrant shall store and control volatile s and gases as required by this subsection.

(1) A registrant or licensee shall store and use a multi-dose container in a properly functioning fume hood.

(2) A registrant or licensee who administers radioactive gases shall do so in a room with a negative pressure vented to the atmosphere.

(3) Any system with which a registrant or licensee administers radioactive gases shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the gas in a shielded container.

(4) A registrant or licensee shall check the operation of any collection system operated pursuant to this section periodically according to the manufacturer's instructions. Records of these checks shall be maintained for a minimum of five (5) years.

(cc) Decay in storage. A registrant or licensee may hold by-product materials with a physical half-life of less than 120 days for decay-in-storage disposal if the requirements of 10 CFR 35.92 are met.

(dd) Use of radioactive material for uptake, dilution or excretion studies.

(1) A registrant or licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution or excretion that is:

(A) Obtained from a person licensed pursuant to 10 CFR 32.72 or equivalent regulations of an Agreement State, a Licensing State or the NRC;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsections (dd)(3) and (ee)(4) of this section, or an individual under the supervision of either as specified insubsection (i) of this section;

(C) Obtained from and prepared by the Department, NRC, Agreement State or Licensing State registrant or licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the registrant or licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

(2) Survey instrument. A registrant or licensee authorized to use radioactive material for uptake, dilution and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with subsection (s) of this section.

(3) Training. Except as provided in subsection (p) of this section, a registrant or licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under subsection (dd)(1) of this section to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (C) of this subdivision and whose certification has been recognized by the NRC or an Agreement State; or

(B) Is an authorized user under subsections (ee)(4) or (ff)(4) of this section, or equivalent Agreement State or NRC requirements; or

(C) Meets the following requirements:

(i) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies that includes:

(a) Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology, and

(b) Work experience, under the supervision of an authorized user who meets the requirements in this subdivision, subsection (ee)(4) or subsection (ff)(4) of this section or equivalent Agreement State or NRC requirements involving ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and administering dosages to patients or human research subjects, and

(ii) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in this subdivision, subsection (ee)(4) or subsection (ff)(4) of this section or equivalent Agreement State, or NRC

requirements, that the individual has satisfactorily completed the requirements in subdivision (3)(C)(i) of this section and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under subdivision (1) of this subsection.

(ee) Use of unsealed radioactive material for which a written direction is not required.

(1) Use of unsealed radioactive material for imaging and localization studies. A registrant or licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in subsection (j) of this section that is:

(A) Obtained from a person licensed pursuant to 10 CFR 35.200 or equivalent regulations of another Agreement State, a Licensing State or the NRC;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection (ee)(4) of this section, or an individual under the supervision of either as specified in subsection (i) of this section;

(C) Obtained from and prepared by a Commissioner-approved, NRC, Agreement State or Licensing State registrant or licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA;

(D) Prepared by the registrant or licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA; or

(E) If the material is a radioactive aerosol or gas, only if the conditions of subsection (bb) of this section are met and if such use is addressed in the registration or license.

(2) Radionuclide contaminants. A registrant or licensee that complies with the following requirements for radioactive drugs is not required to obtain a written directive under subsection (j) of this secion:

(A) The registrant or licensee shall not administer to humans a radioactive drug containing:

(i) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m),

(ii) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride),

(iii) More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82);

(B) To demonstrate compliance with subparagraph (A) of this subdivision, the registrant or licensee preparing radioactive drugs from radionuclide generators shall:

(i) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator, and

(ii) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems;

(C) Retain a record of each measurement in accordance with G.103; and

(D) Report immediately to the Commissioner each occurrence of radionuclide contaminant concentration exceeding the limits specified in subparagraph (A) of this subdivision.

(3) Possession of survey instruments. A registrant or licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with subsection (s) of this section.

(4) Training for imaging and localization studies. Except as provided in subsection (p) of this section, the registrant or licensee shall require an authorized user of unsealed radioactive material for the uses authorized under subsection (ee)(1) of this section to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (C) of this subdivision and whose certification has been recognized by an Agreement State or the NRC;

(B) Is an authorized user under subsection (ff)(4) of this section, or equivalent Agreement State or NRC requirements; or

(C) Meets the following requirements:

(i) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes, at a minimum:

(a) Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; radiation biology, and

(b) Work experience, under the supervision of an authorized user who meets the requirements in this subdivision or subsection (ff)(4) of this section, or equivalent Agreement State or NRC requirements, involving ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; using procedures to contain spilled radioactive material safely and using proper decontamination procedures; administering radiopharmaceutical dosages to patients or human research subjects; and eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity and processing the eluate with reagent kits to prepare labeled radioactive drugs, and

(ii) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in this subdivision or subsection (ff)(4) of this section, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in . subdivision (4)(C)(i) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under subsection (ee)(1) of this section.

(ff) Use of unsealed radioactive material for which a written directive is required.

(1) A registrant or licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that is:

(A) Obtained from a person licensed in accordance with 10 CFR 35.300;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection (ee)(4) or (ff)(4) of

this section or an individual under the supervision of either as specified in subsection (p) of this section;

(C) Obtained from and prepared by a Commissioner-approved, NRC, Agreement State or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(D) Prepared by the registrant or licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

(2) Safety Instruction. In addition to the requirements of section 22a-153-6(b) of the Regulations of Connecticut State Agencies, each registrant or licensee shall:

(A) Provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with subsection (z) of this section. The training must be provided initially and at least annually. The instruction shall be appropriate to the assigned duties of persons receiving instruction and include the following:

(i) Patient or human research subject control, and

(ii) Visitor control that includes routine visitation to hospitalized individuals in accordance with section 22a-153-2 of the Regulations of Connecticut State Agencies; contamination control; waste control; and notification of the RSO, or his or her designee and the authorized user if the patient or the human research subject dies or has a medical emergency; and

(B) Retain a record of individuals receiving instruction in accordance with G.105 .

(3) Safety precautions. Each licensee or registrant shall:

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with subsection (z) of this section:

(i) Quarter the patient or the human research subject either in:

(a) A private room with a private sanitary facility, or

(b) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with subsection (z) of this section,

(ii) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or

human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room, and

(iii) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste; and

(B) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Commissioner in accordance with G.123 if it is possible that any individual could receive exposures in excess of section 22a-153-2(f) of the Regulations of Connecticut State Agencies as a result of the deceased's body.

(3) Possession of survey instruments. A registrant or licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with subsection (s) of this section.

(4) Training. Except as provided in subsection (p) of this section, each registrant or licensee shall require an authorized user of radioactive material for the uses authorized under subdivision (1) of this section to be a physician who meets the requirements in 10 CFR 35.390.

(5) Training for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). Except as provided in subsection (p) of this section, each registrant or licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who meets the requirements of 10 CFR 35.392.

(6) Training for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries). Except as provided in subsection (p) of this section, each registrant or licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who meets the requirements of 10 CFR 35.394.

(gg) Manual brachytherapy.

(1) Use of Sealed Sources. A registrant or licensee shall use only brachytherapy sources for therapeutic medical uses that are either:

(A) Approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of subsection (l)(1)(A) of this section are met.

(2) Surveys after source implant and removal. A registrant or licensee shall:

(A) Immediately after implanting sources in a patient or a human research subject, perform a survey to locate and account for all sources that have not been implanted;

(B) Immediately after removing the last temporary implant source from a patient or a human research subject, make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed; and

(C) Retain a record of the surveys in accordance with G.106.

(3) Brachytherapy sources inventory. Each registrant or licensee shall:

(A) Maintain accountability at all times for all brachytherapy sources in storage or use;

(B) Promptly after removing sources from a patient or a human research subject, return brachytherapy sources to a secure storage area; and

(C) Maintain a record of the brachytherapy source accountability in accordance with G.107.

(4) Safety instruction. In addition to the requirements of section 22a-153-6(b) of the Regulations of Connecticut State Agencies, a registrant or licensee shall:

(A) Provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with subsection (z) of this section. Instruction must be commensurate with the duties of the personnel and shall include the following:

(i) Size and appearance of the brachytherapy sources,

(ii) Safe handling and shielding instructions,

(iii) Patient or human research subject control,

(iv) Visitor control, including routine visitation of hospitalized individuals in accordance with section 22a-153-2(f)(1)(A) of the Regulations of

Connecticut State Agencies and visitation authorized in accordance with section 22a-153-2(f)(2)(B) of the Regulations of Connecticut State Agencies, and

(v) Notification of the RSO, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The registrant or licensee shall also notify the Commissioner in accordance with G.123 if it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body; and

(B) Retain a record of individuals receiving instruction in accordance with G.105.

(5) Safety precautions for patients or human research subjects. Each registrant or licensee shall:

(A) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with subsection (z) of this section:

(i) Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy, and

(ii) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(B) Have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

(i) Dislodged from the patient, or

(ii) Lodged within the patient following removal of the source applicators; and

(C) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

(6) Calibration measurements of brachytherapy sealed sources. Each registrant or licensee:

(A) Prior to the first medical use of a brachytherapy sealed source on or after the effective date of this section, shall perform the following:

(i) Determine the source output or activity using a dosimetry system that meets the requirements of G.76a.,

(ii) Determine source positioning accuracy within applicators, and

(iii) Use published protocols accepted by nationally recognized bodies to meet the requirements of subparagraphs (A)(i) and (A)(ii) of this subdivision;

(B) May use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subparagraph (A) of this subdivision;

(C) Shall mathematically correct the outputs or activities determined in subparagraph (A) of this subdivision for physical decay at intervals consistent with 1.0 percent physical decay;

(D) Shall have an authorized medical physicist perform or review the calculation measurements made pursuant to subparagraphs (A) through (C) of this subdivision;

(E) Shall have only an authorized medical physicist calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined in accordance with subparagraphs (A) through (C) of this subdivision;

(F) Shall retain a record of each calibration in accordance with G.108; and

(G) Shall retain a record of decay calculations required by subparagraph (E) of this subdivision in accordance with G.109.

(7) Therapy-related computer systems. A registrant or licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays; and

(D) The accuracy of the software used to determine radioactive source positions from radiographic images.

(8) Possession of survey instruments. A registrant or licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of

measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with subsection (s) of this section.

(9) Training. Except as provided in subsection (p) of this section, a registrant or licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under subdivision (1) of this subsection to be a physician who meets the requirements of 10 CFR 35.490.

(10) Training for ophthalmic use of strontium-90. Except as provided in subsection (p) of this section, a registrant or licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized undersubdivision (1) of this subsection to be a physician who meets the requirements of 10 CFR 35.491.

(hh) Sealed sources for diagnosis.

(1) A registrant or licensee shall use only sealed sources for diagnostic medical uses that are:

(A) Approved in the Sealed Source and Device Registry; and

(B) Handled in accordance with the manufacturer's radiation safety instructions.

(2) Training. Except as provided in subsection (p) of this section, a registrant or licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under subdivision (1) of this subsection to be a physician, dentist or podiatrist who:

(A) Is certified by a specialty board whose certification process includes all of the requirements in subparagraph (B) of this subdivision and whose certification has been recognized by an Agreement State or the NRC; or

(B) Has had eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

(i) Radiation physics and instrumentation,

(ii) Radiation protection,

(iii) Mathematics pertaining to the use and measurement of radioactivity,

(iv) Radiation biology, and

(v) Training in the use of the device for the uses requested.

(ii) Photon emitting remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

Use of sealed sources in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A registrant or licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption application accepted by the FDA provided the requirements of subsection (l)(1) of this section are met.

(2) Surveys of patients and human research subjects treated with a remote afterloader unit. Each registrant or licensee shall:

(A) Immediately following treatment of a patient or a human research subject and prior to release from registrant or licensee control, make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position; and

(B) Retain a record of the surveys in accordance with subsection (kk)(15) of this section.

(3) Installation, maintenance, adjustment and repair. Each licensee or registrant shall:

(A) Allow only a person specifically licensed by the Commissioner, the NRC or an Agreement State to install, maintain, adjust or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s) or compromise the radiation safety of the unit or the source(s);

(B) Except for low dose-rate remote afterloader units, allow only a person specifically licensed by the Commissioner, an Agreement State, Licensing State or the NRC shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units;

(C) For a low dose-rate remote afterloader unit, allow only a person specifically licensed by the Commissioner, an Agreement State, Licensing State or the NRC,

or an authorized medical physicist shall install, replace, relocate or remove a sealed source(s) contained in the unit; and

(D) Retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units in accordance with subsection (kk)(19) of this section.

(4) Safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

(A) A registrant or licensee shall:

(i) Secure the unit, the console, the console keys and the treatment room when not in use or unattended,

(ii) Permit only individuals approved by the authorized user, Radiation Safety Officer or authorized medical physicist to be present in the treatment room during treatment with the source(s),

(iii) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable, and

(iv) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions,

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure, and

(c) The names and telephone numbers of the authorized users, the authorized medical physicist and the Radiation Safety Officer to be contacted if the unit or console operates abnormally;

(B) A registrant or licensee shall maintain a copy of the procedures required by subdivision (4)(iv) of this subsection at the unit console or a notation where such procedures may be immediately obtained;

(C) A registrant or licensee shall post instructions at the unit console to inform the operator of:

(i) The location of the procedures required by subdivision (4)(iv) of this subsection, and

(ii) The names and telephone numbers of the authorized users, the authorized medical physicist and the RSO to be contacted if the unit or console operates abnormally;

(D) A registrant or licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(i) The procedures identified in subdivision (4)(iv) of this subsection; and

(ii) The operating procedures for the unit.

(E) A registrant or licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A registrant or licensee shall retain a record of individuals receiving instruction required by subsection (D) of this subdivision, in accordance with subsection (kk)(14) of this section.

(5) Safety precautions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units. Each registrant or licensee shall:

(A) Control access to the treatment room by a door at each entrance;

(B) Equip each entrance to the treatment room with an electrical interlock system that will:

(i) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(ii) Cause the source(s) to be shielded promptly when an entrance door is opened; and

(iii) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console;

(C) Require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels;

(D) Except for low-dose remote afterloader units, construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation;

(E) For licensed activities where sources are placed within the patient's or human research subject's body, only conduct treatments which allow for expeditious removal of a decoupled or jammed source;

(F) In addition to the requirements specified in subparagraphs (A) through (E) of this subdivision

(i) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit, and

(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit,

(ii) For high dose-rate remote afterloader units, require:

(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit, and

(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit,

(iii) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit, and

(iv) Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies; and

(G) Have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

(i) Remains in the unshielded position; or

(ii) Lodges within the patient following completion of the treatment.

(6) Dosimetry equipment. Each registrant or licensee shall:

(A) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met;

(i) The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two (2) years and after any servicing that may have affected system calibration, or

(ii) The system shall have been calibrated within the previous four (4) years; 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility;

(B) Have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subparagraph (A) of this subdivision. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subparagraph (A) of this subdivision; and

(C) Retain a record of each calibration, intercomparison, and comparison in accordance with subdivision (kk)(20) of this section.

(7) Full calibration measurements on teletherapy units. Each registrant or licensee shall:

(A**)** If authorized to use a teletherapy unit for medical use, perform full calibration measurements on each teletherapy unit:

(i) Before the first medical use of the unit, and

(ii) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than +\-5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay,

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location, and

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly, and

(iii) At intervals not exceeding one year;

(B) To satisfy the requirement of subparagraph (A) of this subdivision, full calibration measurements shall include determination of:

(i) The output within C3 percent for the range of field sizes and for the distance or range of distances used for medical use,

(ii) The coincidence of the radiation field and the field indicated by the light beam localizing device,

(iii) The uniformity of the radiation field and its dependence on the orientation of the useful beam,

(iv) Timer accuracy and linearity over the range of use,

(v) On-off error, and

(vi) The accuracy of all distance measuring and localization devices in medical use;

(C) Use the dosimetry system described in subdivision (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(i) of this subdivision may be made using a dosimetry system that indicates relative dose rates;

(D) Make full calibration measurements required by subparagraph (A) of this subdivision in accordance with published protocols accepted by nationally recognized bodies;

(E) Mathematically correct the outputs determined in subparagraph (B)(i) of this subdivision for physical decay for intervals not exceeding one month for cobalt-60, 6 months for cesium-137, or at intervals consistent with one percent decay for all other nuclides;

(F) Full calibration measurements required by subparagraph (A) of this subdivision and physical decay corrections required by subparagraph (E) of this subdivision shall be performed by the authorized medical physicist; and

(G) Retain a record of each calibration in accordance with subdivision (kk)(21) of this section.

(8) Full calibration measurements on remote afterloader units. Each registrant or licensee shall:

(A) If authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(i) Before the first medical use of the unit,

(ii) Before medical use under the following conditions:

(a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility, and

(b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly,

(iii) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days, and

(iv) At intervals not exceeding 1 year for low dose-rate remote afterloader units;

(B) To satisfy the requirement of subparagraph (A) of this subdivision, full calibration measurements shall include, as applicable, determination of:

(i) The output within +/- 5 percent,

(ii) Source positioning accuracy to within +/- one millimeter,

(iii) Source retraction with backup battery upon power failure,

(iv) Length of the source transfer tubes,

(v) Timer accuracy and linearity over the typical range of use,

(vi) Length of the applicators, and

(vii) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces;

(C) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subparagraph (B) of this subdivision, perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter;

(D) Use the dosimetry system described in subdivision (6)(A) of this section to measure the output;

(E) Make full calibration measurements required by subparagraph (A) of this subdivision in accordance with published protocols accepted by nationally recognized bodies;

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subparagraphs (A) though (E) of this subdivision;

(G) Mathematically correct the outputs determined in subparagraph (B)(i) of this subdivision for physical decay at intervals consistent with +/- one percent physical decay;

(H) Full calibration measurements required by subparagraph (A) of this subdivision and physical decay corrections required bysubparagraph (G) of this subdivision shall be performed by the authorized medical physicist; and

(I) Retain a record of each calibration in accordance with subdivision (kk)(21) of this section.

(9) Full calibration measurements on gamma stereotactic radiosurgery units. Each registrant or licensee shall:

(A) If authorized to use a gamma stereotactic radiosurgery unit for medical use, perform full calibration measurements on each unit:

(i) Before the first medical use of the unit,

(ii) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay,

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location, and

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly, and

(iii) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet;

(B) To satisfy the requirement of subparagraph (A) of this subdivision, full calibration measurements must include determination of:

(i) The output within +/-3 percent,

(ii) Relative helmet factors,

(iii) Isocenter coincidence,

(iv) Timer accuracy and linearity over the range of use,

(v) On-off error,

(vi) Trunnion centricity,

(vii) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off,

(viii) Helmet microswitchs,

(ix) Emergency timing circuits, and

(x) Stereotactic frames and localizing devices (trunnions);

(C) Use the dosimetry system described in subdivision (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation

measurements required in subparagraph (B)(i) of this subdivision may be made using a dosimetry system that indicates relative dose rates;

(D) Make full calibration measurements required by subparagraph (A) of this subdivision in accordance with published protocols accepted by nationally recognized bodies;

(E) Mathematically correct the outputs determined in subparagraph (B)(i) of this subdivision at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides; and

(F) Full calibration measurements required by subparagraph (A) of this subdivision and physical decay corrections required by subparagraph (E) of this subdivision shall be performed by the authorized medical physicist; and

(G) Retain a record of each calibration in accordance with subdivision (kk)(21) of this section.

(10) Periodic spot-checks for teletherapy units. Each licensee or registrant shall:

(A) If authorized to use teletherapy units for medical use, perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(i) Timer accuracy and timer linearity over the range of use,

(ii) On-off error,

(iii) The coincidence of the radiation field and the field indicated by the light beam localizing device,

(iv) The accuracy of all distance measuring and localization devices used for medical use,

(v) The output for one typical set of operating conditions measured with the dosimetry system described in subdivision (6)(B) of this subsection, and

(vi) The value obtained at last full calibration corrected mathematically for physical decay by calculating the difference between the measurement made in subparagraph (A)(v) of this subdivision and the anticipated output, expressed as a percentage of the anticipated output;

(B) Perform measurements required by subparagraph (A) of this subdivision in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements;

(C) Have the authorized medical physicist review the results of each spot-check within fifteen days. The authorized medical physicist shall promptly notify the registrant or licensee in writing of the results of each spot-check;

(D) If authorized to use a teletherapy unit for medical use, perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(i) Electrical interlocks at each teletherapy room entrance,

(ii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism),

(iii) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility,

(iv) Viewing and intercom systems,

(v) Treatment room doors from inside and outside the treatment room, and

(vi) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off;

(E) If the results of the checks required in subparagraph (D) of this subdivision indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(F) Retain a record of each spot-check required by subparagraph (A) of this subdivision and subparagraph (D) of this subdivision, in accordance with subdivision (kk)(22) of this section.

(11) Periodic spot-checks for remote afterloader units. Each registrant or licensee shall:

(A) If authorized to use remote afterloader units for medical use, perform spot-checks of each remote afterloader facility and on each unit:

(i) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit,

(ii) Prior to each patient treatment with a low dose-rate remote afterloader unit, and

(iii) After each source installation;

(B) Have the authorized medical physicist establish written procedures for performing the spot-checks required in subparagraph (A) of this subdivision. The authorized medical physicist need not actually perform the spot-check measurements;

(C) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check;

(D) To satisfy the requirements of subparagraph (A) of this subdivision, spot-checks must, at a minimum, assure proper operation of:

(i) Electrical interlocks at each remote afterloader unit room entrance,

(ii) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility, and

(iii) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility,

(iv) Emergency response equipment,

(v) Radiation monitors used to indicate the source position,

(vi) Timer accuracy,

(vii) Date and time in the unit's computer, and

(viii) Decayed source(s) activity in the unit's computer;

(E) If the results of the checks required in subparagraph (D) of this subdivision indicate the malfunction of any system, lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(F) Retain a record of each check required by subparagraph (D) of this subdivision in accordance with subdivision (kk)(23) of this section.

(12) Periodic spot-checks for gamma stereotactic radiosurgery units. Each licensee or registrant shall:

(A) If authorized to use a gamma stereotactic radiosurgery unit for medical use, perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(i) Monthly,

(ii) At the beginning of each day of use, and

(iii) After each source installation;

(B) Have the authorized medical physicist:

(i) Establish written procedures for performing the spot-checks required in subparagraph (A) of this subdivision, and

(ii) Review the results of each spot-check required by subparagraph (A)(i) of this subdivision within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the registrant or licensee as soon as possible, in writing, of the results of the spot check;

(C) To satisfy the requirements of subparagraph (A)(i) of this subdivision spot-checks shall, at a minimum:

(i) Assure proper operation of:

(a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off,

(b) Helmet microswitchs,

(c) Emergency timing circuits, and

(d) Stereotactic frames and localizing devices (trunnions), and

(ii) Determine:

(a) The output for one typical set of operating conditions measured with the dosimetry system described in subdivision (6)(B) of this subsection,

(b) The difference between the measurement made in subparagraph (C)(ii)(a) of this subdivision and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay),

(c) Source output against computer calculation,

(d) Timer accuracy and linearity over the range of use,

(e) On-off error, and

(f) Trunnion centricity;

(D) To satisfy the requirements of subparagraphs (A)(ii) and (A)(iii) of this subdivision, spot-checks shall assure proper operation of:

(i) Electrical interlocks at each gamma stereotactic radiosurgery room entrance,

(ii) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility,

(iii) Viewing and intercom systems,

(iv) Timer termination,

(v) Radiation monitors used to indicate room exposures, and

(vi) Emergency off buttons;

(E) Arrange for prompt repair of any system identified in subparagraph (C) of this subdivision that is not operating properly;

(F) If the results of the checks required in subparagraph (D) of this subdivision indicate the malfunction of any system, lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(G) Retain a record of each check required by subparagraphs (C) and (D) of this subdivision in accordance with subdivision (kk)(24) of this section.

(13) Additional technical requirements for mobile remote afterloader units._Each registrant or licensee shall:

(A) If providing mobile remote afterloader service:

(i) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent, and

(ii) Account for all sources before departure from a client's address of use;

(B) In addition to the periodic spot-checks required by subdivision (11) of this subsection, if authorized to use mobile afterloaders for medical use, perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:

(i) Electrical interlocks on treatment area access points,

(ii) Source exposure indicator lights on the remote afterloader unit, on the control console and in the facility,

(iii) Viewing and intercom systems,

(iv) Applicators, source transfer tubes and transfer tube-applicator interfaces,

(v) Radiation monitors used to indicate room exposures,

(vi) Source positioning accuracy, and

(vii) Radiation monitors used to indicate whether the source has returned to a safe shielded position;

(C) In addition to the requirements for checks in subparagraph (B) of this subdivision, ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use;

(D) If the results of the checks required in subparagraph (B) of this subdivision indicate the malfunction of any system, lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system; and

(E) Retain a record of each check required by subparagraph (B) of this subdivision in accordance with subdivision (kk)(25) of this section.

(14) Radiation surveys. Each registrant or licensee shall:

(A) In addition to the survey requirements in section 22a-153-2(h) of the Regulations of Connecticut State Agencies, perform surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry;

(B) Make the survey required by subparagraph (A) of this subdivision at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s) or compromise the radiation safety of the unit or the source(s); and

(C) Retain a record of the radiation surveys required by subparagraph (A) of this subdivision in accordance with subdivision (kk)(26) of this section.

(15) Five-year inspection for teletherapy and gamma stereotactic radiosurgery units. Each registrant or licensee shall:

(A) Have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism;

(B) Inspection and servicing required by subparagraph (A) of this subdivision shall only be performed by persons specifically licensed to do so by the Commissioner, an Agreement State, a Licensing State or the NRC; and

(C) Record the inspection and servicing in accordance with subsection (kk)(27) of this section.

(16) Therapy-related computer systems. Each registrant or licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(E) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(17) Training for use of remote afterloader units, teletherapy units and gamma sterotactic radiosurgery units. Except as provided in subsection (p) of this section, each registrant or licensee shall require an authorized user of a sealed source for a use authorized under subsection (ii)(1) of this section to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (B) of this subdivision and whose certification has been recognized by an Agreement State or the NRC; or

(B) Meets the following requirements:

(i) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes 200 hours of classroom and laboratory training in the areas of radiation physics and instrumentation; radiation protection;

mathematics pertaining to the use and measurement of radioactivity; and radiation biology,

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this subdivision or equivalent Agreement State or NRC requirements at a medical institution, involving:

(a) Reviewing full calibration measurements and periodic spot checks,

(b) Preparing treatment plans and calculating treatment doses and times,

(c) Using administrative controls to prevent a medical event involving the use of radioactive material,

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console,

(e) Checking and using survey meters, and

(f) Selecting the proper dose and how it is to be administered,

(iii) Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this subdivision or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph (B)(ii) of this subdivision, and

(iv) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in this subdivision, equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in (B)(i) and (B)(ii) of this subdivision and has achieved a level of competency sufficient to function independently as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.

(jj) Other medical uses of radioactive material or radiation from radioactive material. A registrant or licensee may use radioactive material or a radiation source approved for medical use that is not otherwise specifically addressed in this section if:

(1) The applicant, registrant or licensee has submitted the information required by subsection (d)(4) of this section; and

(2) The applicant, registrant or licensee has received written approval from the NRC, an Agreement State or Licensing State in a registration or license and uses the material in accordance with the applicable regulations and registration or license, specific conditions, the NRC, Agreement State or Licensing State considers necessary for the medical use of the material.

(kk) Records.

(1) Unless otherwise specified in this subsection, each registrant or licensee shall maintain any record required by this section for a period of five (5) years.

(2) Records of authority and responsibilities for radiation protection programs. Each registrant or licensee shall:

(A) Retain a record of actions taken by the registrant or licensee's management in accordance with subsection (f)(1) including a summary of the actions taken and a signature of licensee management;

(B) Retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by subsection (f)(4) of this section, and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by subsection (f)(2) of this section with the signature of the Radiation Safety Officer and licensee management; and

(C) The minutes of each Radiation Safety Committee meeting held in accordance with subsection (f)(7) of this section shall include:

(i) The date of the meeting,

(ii) Members present,

(iii) Members absent, and

(iv) Summary of deliberations and discussions.

(3) Records of radiation protection program safety changes. Records made in accordance with subsection (g)(1) of this section shall include a copy of the old and new procedures, the effective date of the change and the signature of the licensee management that reviewed and approved the change.

(4) Records of medical events. Each registrant or licensee shall retain a record of any medical event reported in accordance with subsection (ll)(1) of this section and shall include the following information:

(A) The registrant or licensee's name;

(B) Names of the individuals involved;

(C) The social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event;

(D) A brief description of the event indicating its cause;

(E) The effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and,

(F) Whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(5) Record of a dose to an embryo/fetus or a nursing child. A record of a dose to an embryo/fetus or a nursing child reported in accordance with subsection (ll)(2) of this section shall include the licensee's name, names of all the individuals involved, social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event including the cause; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(6) Records of calibrations of instruments used to measure the activity of unsealed radioactive material. Records of instrument calibrations required by subsection (r) of this section shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration and the name of the individual who performed the calibration.

(7) Records of survey instrument calibrations. Records of survey instrument calibrations required by subsection (s) of this section shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration and the name of the individual who performed the calibration.

(8) Records of dosages of unsealed radioactive material for medical use. Records of dosage determinations required by subsection (t) of this section shall include the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(9) Records of possession of sealed sources and brachytherapy sources. Records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by subsection (v)(4)of this section shall include the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(10) Records of surveys for ambient radiation exposure rate. Records of each survey required by subsection (y) of this section shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(11) Records of the release of individuals containing radioactive drugs or implants containing radioactive material. A registrant or licensee shall:

(A) Retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for five (5) years after the date of release; and

(B) Retain a record, for five (5) years after the date of release, that the instructions required by subsection (z) of this section were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 1 millisievert (0.1 rem).

(12) Records of decay-in-storage. Records of the disposal of licensed materials, as required by subsection (cc) of this section, shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container and the name of the individual who performed the survey.

(13) Records of radionuclide purity. Records of the radionuclide contaminant concentration tests required by subsection (ee)(2) of this section shall include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement and the name of the individual who made the measurement.

(14) Records of safety instruction and training. Records of safety instructions and training required by subsections (ff)(2), (gg)(4) and (u)(4) of this section shall include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s) and the name(s) of the individual(s) who provided the instruction.

(15) Records of radiation surveys of patients and human research subjects. Records of the surveys required by subsections (gg)(2) and (ii)(2) of this section shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(16) Records of brachytherapy source inventory.
Records of brachytherapy source accountability required by subsection (gg)(3) of this section shall include:

(A) For temporary implants:

(i) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage and the location of use; and

(ii) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage; and

(B) For permanent implants:

(i) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(ii) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(iii) The number and activity of sources permanently implanted in the patient or human research subject.

(17) Records of calibration measurements on brachytherapy sources. Records of the calibrations on brachytherapy sources required by subsection (gg)(6) of this section shall include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(18) Records of decay of strontium-90 sources for ophthalmic treatments. Records of the activity of a strontium-90 source required by subsection (gg)(6) of this section shall be maintained for the life of the source and shall include:

(A) The date and initial activity of the source as determined under subsection (gg)(6) of this section; and

(B) For each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

(19) Records of installation, maintenance, adjustment and repair. Records of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma

stereotactic radiosurgery units required by subsection (ii)(3) of this section shall include the date, description of the service and name(s) of the individual(s) who performed the work.

(20) Records of dosimetry equipment.

(A) Records of the calibration, intercomparison and comparisons of dosimetry equipment done in accordance with subsection (ii)(6) of this section shall be retained for the duration of the registration or license; and

(B) For each calibration, intercomparison or comparison, each record shall include:

(i) The date,

(ii) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by subsections (ii)(6)(A) and (B) of this section,

(iii) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, and

(iv) The names of the individuals who performed the calibration, intercomparison or comparison.

(21) Records of teletherapy remote afterloader and gamma stereotactic radiosurgery full calibrations._ Records of the teletherapy, remote afterloader and gamma stereotactic radiosurgery full calibrations required by subsections (ii)(7), (ii)(8) and (ii)(9) of this section shall include:

(A) The date of the calibration,

(B) The manufacturer's name, model number and serial number for the teletherapy, remote afterloader and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit,

(C) The results and assessments of the full calibrations,

(D) The results of the autoradiograph required for low dose-rate remote afterloader units, and

(E) The signature of the authorized medical physicist who performed the full calibration.

(22) Records of periodic spot-checks for teletherapy units. Records of each periodic spot-check for teletherapy units required by subsection (ii)(10) of this section shall include:

(A) The date of the spot-check;

(B) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(C) An assessment of timer linearity and constancy;

(D) The calculated on-off error;

(E) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(F) The determined accuracy of each distance measuring and localization device;

(G) The difference between the anticipated output and the measured output;

(H) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(I) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(23) Records of periodic spot-checks for remote afterloader units. Records of each spot-check for remote afterloader units required by subsection (ii)(11) of this section shall include, as applicable:

(A) The date of the spot-check;

(B) The manufacturer's name, model number and serial number for the remote afterloader unit and source;

(C) An assessment of timer accuracy;

(D) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems and clock and decayed source activity in the unit's computer; and

(E) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(24) Records of periodic spot-checks for gamma stereotactic radiosurgery units. Records of each spot-check for gamma stereotactic radiosurgery units required by subsection (ii)(12) of this section shall include, as applicable:

(A) The date of the spot-check;

(B) The manufacturer's name, model number and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(C) An assessment of timer linearity and accuracy;

(D) The calculated on-off error;

(E) A determination of trunnion centricity;

(F) The difference between the anticipated output and the measured output;

(G) An assessment of source output against computer calculations;

(H) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism and stereotactic frames and localizing devices (trunnions); and

(I) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(25) Records of additional technical requirements for mobile remote afterloader units.

Records of each check for mobile remote afterloader units required by subsection (ii)(13) shall include:

(A) The date of the check;

(B) The manufacturer's name, model number and serial number of the remote afterloader unit;

(C) Notations accounting for all sources before the licensee departs from a facility;

(D) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

(E) The signature of the individual who performed the check.

(26) Records of surveys of therapeutic treatment units.

(A) Records of radiation surveys of treatment units made in accordance with subsection (ii)(14) of this section shall be maintained for the duration of use of the unit; and

(B) Each record shall include:

(i) The date of the measurements,

(ii) The manufacturer's name, model number and serial number of the treatment unit, source and instrument used to measure radiation levels,

(iii) Each dose rate measured around the source while the unit is in the off position and the average of all measurements, and

(iv) The signature of the individual who performed the test.

(27) Records of 5-year inspection for teletherapy and gamma stereotactic surgery units.

(A) Records of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by subsection (ii)(15) of this section shall be maintained for the duration of use of the unit; and

(B) Each record shall include:

(i) The inspector's radioactive materials license number,

(ii) The date of inspection,

(iii) The manufacturer's name and model number and serial number of both the treatment unit and source,

(iv) A list of components inspected and serviced, and the type of service, and

(v) The signature of the inspector.

(ll**) Reports.**

(1) Reports and notifications of medical events. Each licensee or registrant shall:

(A) Other than events that result from intervention by a patient or human research subject, report any event in which the administration of radioactive material or radiation from radioactive material results in:

(i) A dose that differs from the prescribed dose by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and either:

(aa) The total dose delivered differs from the prescribed dose by 20 percent or more,

(bb) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range, or

(cc) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more,

(ii) A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:

(aa) An administration of a wrong radioactive drug,

(bb) An administration of a radioactive drug containing radioactive material by the wrong route of administration,

(cc) An administration of a dose or dosage to the wrong individual or human research subject,

(dd) An administration of a dose or dosage delivered by the wrong mode of treatment, or

(ee) A leaking sealed source, and

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;

(B) Report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician;

(C) Notify the Commissioner by telephone no later than the next calendar day after discovery of the medical event;

(D) Submit a written report to the Commissioner within 15 days after discovery of the medical event, as follows:

(i) The written report shall include:

(aa) The licensee's name,

(bb) The name of the prescribing physician,

(cc) A brief description of the event,

(dd) Why the event occurred,

(ee) The effect, if any, on the individual who received the administration,

(ff) Actions, if any, that have been taken, or are planned, to prevent recurrence, and

(gg) Certification that the registrant or licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not, and

(ii) The report shall not contain the individual's name or any other information that could lead to identification of the individual,

(E) Provide notification of any medical event not caused by the individual who is the submit of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant or licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant or licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant or licensee shall notify the individual as soon as possible thereafter. The registrant or licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant or licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant or licensee upon request. The registrant or licensee shall provide such a written description if requested;

(F) Aside from the notification requirement, nothing in this section affects any rights or duties of registrants, licensees and physicians in relation to each other, to

individuals affected by the medical event or to that individual's responsible relatives or guardians; and

(G) Retain a record of a medical event in accordance with subsection (kk)(4) of this section. A copy of the record required under subsection (kk)(4) of this section shall be provided to the referring physician if other than the registrant or licensee, within 15 days after discovery of the medical event.

(2) Report and notification of a dose to an embryo/fetus or a nursing child. Each licensee or registrant shall:

(A) Report any dose to an embryo/fetus that is greater than 5 millisievert (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user;

(B) Report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(i) Is greater than five (5) millisievert (500 mrem) total effective dose equivalent, or

(ii) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician;

(C) Notify by telephone the Commissioner no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report insubdivision (2)(A) or (2)(B) of this subsection;

(D) The licensee shall submit a written report to the Commissioner within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subdivision (2)(A) or (2)(B) of this subsection:

(i) The written report shall include:

(aa) The registrant or licensee's name,

(bb) The name of the prescribing physician,

(cc) A brief description of the event,

(dd)Why the event occurred,

(ee) The effect on the embryo/fetus or the nursing child,

(ff) What actions, if any, have been taken, or are planned, to prevent recurrence, and

(gg) Certification that the registrant or licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not, and

(ii) The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child;

(E) Notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subdivision (2)(A) or (2)(B) of this subsection, unless the referring physician personally informs the registrant or licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The registrant or licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the registrant or licensee shall make the appropriate notifications as soon as possible thereafter. The registrant or licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the registrant or licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the registrant or licensee upon request. The registrant or licensee shall provide such a written description if requested; and

(F) Retain a record of a dose to an embryo/fetus or a nursing child in accordance with subsection (kk)(5) of this section. A copy of the record required under subsection (kk)(5) of this section shall be provided to the referring physician, if other than the registrant or licensee, within 15 days after discovery of the event.

(3) Reports of leaking sources. A registrant or licensee shall file a report with the Commissioner within five (5) days if a leakage test required by subsection (v) of this section reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report shall include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(4) Reports of patient departure prior to authorized release. Each registrant or licensee shall:

(A) Notify the Commissioner by telephone immediately upon discovery that a patient or human research subject has departed from the registrant or licensee's facility without authorization under subsection (z) of this section; and

(B) Submit a written report to the Commissioner within 30 days after discovery of the unauthorized departure. The written report shall include:

(i) The registrant or licensee's name,

(ii) The date and time of the unauthorized departure,

(iii) The projected date and time when release would have occurred,

(iv) The radionuclide, chemical and physical form and calculated activity at time of release, and

(v) The apparent reason(s) for the departure prior to authorized release .

(5) Notification of deceased patients or human research subjects containing radioactive material. Each registrant or licensee shall:

(A) Notify the Commissioner by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, when it is possible that any individual could receive exposures in excess of section 22a-153-2(f) of the Regulations of Connecticut State Agencies as a result of the deceased's body; and

(B) Submit a written report to the Commissioner within 30 days after discovery that the patient or human research subject referenced in subdivision (2)(A) of this subsection has died. The written report shall include:

(i) The registrant or licensee's name,

(ii) The date of death, and

(iii) The radionuclide, chemical and physical form and calculated activity at time of death.

Statement of Purpose: This section establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of

registrations and licenses authorizing these activities in order to provide for the radiation safety of workers, the general public, patients and human research subjects.